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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
STOKLOSA, JOSEPH A	

ART UNIT	PAPER NUMBER
3762	

MAIL DATE	DELIVERY MODE
09/30/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/761,424	CARROLL ET AL.	
	Examiner	Art Unit	
	JOSEPH STOKLOSA	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 September 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7,8,15-19,21 and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7,8,15-19,21 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/10/2010 has been entered.

Response to Amendment

2. The declaration under 37 CFR 1.132 filed 3/10/2010 is insufficient to overcome the rejection of claims 1-5, 7-8, 15-19, and 21-22 based upon Reiss in view of Holsheimer as set forth in the last Office action because:

3. Examiner notes, the considered rule 132 declaration appears to lack sufficient evidence that Applicant's invention will provide the beat frequency signal that will avoid remaining in and shunting through the CSF and thereby recruit dorsal column fibers. In other words Applicant has alleged that avoidance of remaining in and shunting through the CSF is paramount to avoid creating discomfort/pain within the thoracic cavity of the patient; however the declaration fails to address this key limitation of the beat frequency avoiding remaining in and shunting through the CSF. Examiner request Applicant further explain this limitation and provide a line citation from within the rule 132 declaration that addresses this.

4. Further, the declaration fails to provide any indication that the achieved beat frequency signal being configured to achieve deeper penetration levels is the result of implanted electrodes. Therefore, Examiner considers the disclosed prior art of Reiss, which discloses interferential stimulation, to also be capable of achieving the same depth of penetration.

5. Additionally, Applicant's declaration Exhibit B, relates to electrodes implanted directly on the Gracile nucleus and directly within the pyramidal tract. Examiner considers this to have sufficiently narrowed the scope of the invention, as the electrodes are not simply implanted within the Dura matter in the epidural space.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-5, 7-8, 15-19, 21-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has failed to provide support within the written specification, as originally filed, for the newly added claim limitation, "and wherein a majority of the at least one beat frequency signal is directionally distributed and controlled, enabling the at least one beat frequency signal to avoid remaining in and shunting through cerebrospinal fluid proximate to the subject's

spinal cord, thereby recruiting dorsal column fibers" in combination with the other claimed elements. Applicant's specification makes no mention of the beat frequency signal being configured to avoid remaining in and shunting through CSF proximate to the subject's spinal cord.

8. Applicant alleges support for the newly added claim limitation based on the following cited specification passages: page 2, lines 11-21, page 3, lines 15-23, and page 6, lines 15-20.

9. Page 2, lines 11-21 are directed to a background section discussing conventional spinal cord stimulation systems that do not use interferential stimulation and states, "most of the current remains in the CSF." Examiner considers this to be a statement with regard to the current state of the prior art, but in no way does this passage convey support that Applicant's invention will provide for "a majority of the at least one beat frequency signal is directionally distributed and controlled, enabling the at least one beat frequency signal to avoid remaining in and shunting through cerebrospinal fluid proximate to the subject's spinal cord, thereby recruiting dorsal column fibers."

10. Page 3, lines 15-23 state;

> "The amplitude can be, modulated in the respective circuits to increase the area of targeted stimulation. This type of current (Interferential) provides improved directional control, decreased accommodation / habituation and increased depth of penetration in comparison to other standard implantable stimulation systems and their accompanying surgical leads. The amplitudes of the outputs in the respective circuits may be modulated to increase the area of targeted stimulation.

> Interferential current allows improved directional control and depth of penetration in comparison to other stimulation techniques."

11. Examiner considers the above passage to simply teach the benefit of interferential stimulation for providing increased directional control and depth of penetration. In no way does the above passage implicitly or explicitly disclose "a majority of the at least one beat frequency signal is directionally distributed and controlled, enabling the at least one beat frequency signal to avoid remaining in and shunting through cerebrospinal fluid proximate to the subject's spinal cord, thereby recruiting dorsal column fibers." It is unclear how the above passage can be read to imply any affect of the beat frequency avoiding remaining within and shunting through CSF when there is no mention of the CSF affect at all in the above passage.

12. Page 6, lines 15-20 state;

> "The digital signal processor 102 improves the accuracy and reliability of digital signals. The digital signal processor 102 processes the multiple pulses 116 from the signal generating source 104 to approximate a sine-wave (pseudo-sine-wave or sine-wave-like). Thus, that type of current recruits larger numbers of dorsal column fibers and provides greater levels of pain relief."

13. Examiner considers the above passage to teach only that a sine-wave/pseudo-sine-wave/sine-wave like signal recruits larger numbers of dorsal column fibers and provides greater levels of pain relief. The above passage fails to implicitly or explicitly disclose in any way that "a majority of the at least one beat frequency signal is directionally distributed and controlled, enabling the at least one beat frequency signal

to avoid remaining in and shunting through cerebrospinal fluid proximate to the subject's spinal cord, thereby recruiting dorsal column fibers." The above passage makes no mention of the beat frequency let alone the beat frequency being directed to avoid remaining in and shunting through the CSF.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 1-5, 7-8, 15-19, 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiss (US 5,512,057) in view of Holsheimer et al. (US 5,643,330).

16. Reiss discloses an interferential spinal cord stimulation system with at least two pairs of electrodes (e.g. Fig. 1 and Col. 3, line 35-39), a sinusoidal pulse generator (e.g. Col. 2, line 13), stimulation frequencies greater than 500hz and less than 20Khz, and wherein the electrode pairs create a beat frequency proximate the subject's spinal cord (e.g. Col. 2, line 3-17).

17. Reiss fails to explicitly teach the use of implantable electrodes. Holsheimer teaches that it is known to use electrodes implanted to the dura matter for use in interferential spinal cord stimulation as set forth in ABSTRACT for providing the predictable results of decreasing power consumption by placing the electrode on the actual stimulation site as well as ensuring/maintaining proper placement of the electrodes in chronic stimulation patients. It would have been obvious to one having

ordinary skill in the art at the time the invention was made to modify the system as taught by Reiss with electrodes implanted to the dura matter since such a modification would provide the predictable results of decreasing power consumption by placing the electrode on the actual stimulation site as well as ensuring/maintaining proper placement of the electrodes in chronic stimulation patients.

18. Examiner considers the invention as taught by Reiss in view of Holsheimer to sufficiently meet applicant's newly added claim limitations of "a majority of the at least one beat frequency signal is directionally distributed and controlled, enabling the at least one beat frequency signal to avoid remaining in and shunting through cerebrospinal fluid proximate to the subject's spinal cord, thereby recruiting dorsal column fibers" since Reiss in view of Holsheimer teach a system for interferential stimulation with implanted electrodes and meet all claimed stimulation parameter limitations, so therefore Examiner considers the system as taught by Reiss in view of Holsheimer to be capable of providing that "a majority of the at least one beat frequency signal is directionally distributed and controlled, enabling the at least one beat frequency signal to avoid remaining in and shunting through cerebrospinal fluid proximate to the subject's spinal cord, thereby recruiting dorsal column fibers."

19. With regard to claim 2, Reiss discloses a digital to analog circuit associated with the microcontroller for generating digital signal pulses (e.g. Fig. 5B).

20. With regard to claim 3, Reiss discloses a programmable gate array integrated circuit (e.g. Col. 4, line 47-65).

21. With regard to claim 4, Reiss discloses the beat frequency is optimally only 200Hz (e.g. Col. 2, line 3-17).

22. With regard to claim 5, Reiss discloses no more than 11 volts being outputted (e.g. Col. 4, line 3-9).

23. With regard to claim 7, Reiss discloses the pulse width of the interferential signal to be no more than 500 microseconds (e.g. Col. 2, line 3-17).

24. With regard to claim 8 and 22, Reiss in view of Holsheimer disclose the invention as claimed but fail to explicitly teach the use of quadripolar electrodes. Examiner takes the position that it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Reiss in view of Holsheimer with use of quadripolar electrodes since such a modification would provide the predictable results of effective and efficient stimulation as well as facilitating controlling and directing the interferential field to the target site.

Response to Arguments

25. Applicant's arguments with respect to claims 1-5, 7-8, 15-19, and 21-22 have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment.

26. Applicant argues that implanted electrodes do not provide the predictable result of decreasing power consumption compared to surface electrode configurations. Examiner cites Scheiner et al. (US 5,466,247) as evidence that power consumption is reduced through use of implanted electrodes opposed to surface electrodes. Scheiner explicitly teaches, "surface electrodes require relatively high current as compared to

implanted electrodes to successfully activate the nerve fibers..." as set forth in Col. 2, line 10-22.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOSEPH STOKLOSA whose telephone number is (571)272-1213. The examiner can normally be reached on Monday-Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Niketa Patel can be reached on 571-272-4156. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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9/21/2010